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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,596	08/19/2003	Choo Yuen May	3587-0110P	2776
2292	7590	12/16/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			SINGH, JAI P	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/642,596	MAY ET AL.	
	Examiner	Art Unit	
	Jai P. Singh	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-13 are pending. Elected group I (claims 1-12) are examined in this office action. Invention of group II is withdrawn from consideration as non-elected invention. No claims are allowed at this time.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to a method of extraction of phytosterols, squalene and vitamin E from crude palm oil.
- II. Claim 13, drawn to phytosterol crystals.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case phytosterols and vitamin E are extracted using super critical fluid extraction process and purified by chromatography.

During a telephone conversation with Mr. Joe McKinney Muncy on November 18, 2005 a provisional election was made without traverse to prosecute the invention of

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group I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claim 13 was withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

Information disclosure statement was not filed by the applicant.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply: The phrase "second short path distillation" in claim 3, step (e) comprising of the distillation of the distillate obtained from claim 2 (first short path distillation). In the specification, the second short

distillation was carried out on phytonutrient enriched "residue". This creates confusion about whether the "residue" being distilled or the "distillate" being distilled at this step (second short path distillation).

The claims 1-12 points out that the method of extraction of phytosterols, squalene and vitamin E from crude palm oil involves three short path distillations in sequence. The first short path distillation was carried out on esterified crude palm oil. The second and third short path distillations were carried out in sequence on distillates obtained from first and second short path distillations respectively. The distillate obtained from third short path distillation was saponified and then phytosterols were purified via extraction and crystallization.

The specification states that the second short path distillation was carried out on the "residue" obtained from the first short path distillation. The distillate from the second short path distillation was then subjected to third short path distillation and the distillate obtained was saponified and then phytosterols were extracted and crystallized. This created a confusion as which steps are being followed for second short path distillation (from "residue" or from "distillate" obtained from first short path distillation).

A further clarification of the steps involved in distillation of "residue" or "distillate" obtained from first short path distillation is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirschenbauer (US Patent 2,598,269), Jacobs (US Patent 6,838,104) and Robinson et al. (6,057,462). Prior art teaches about the isolation of sterols and phytosterols from fatty materials and tall oil respectively which embraces applicant's claimed invention.

Kirschenbauer disclose about the recovery of sterols present in fatty materials using molecular distillation of the natural fats and oils then recovering the volatile unsaponifiables from the distillate. In this process the fatty material is treated at low temperatures with a suitable monohydric alcohol (methyl alcohol, ethyl alcohol) in presence of an alkaline catalyst sodium hydroxide or potassium hydroxide. During this reaction the triglycerides of fats and oil are converted to more volatile fatty acid esters of monohydric alcohols (see the entire document especially column 3, lines 28-53).

The reaction mixture from esterification reaction (above) is then distilled either by batch or continuous distillation process to remove unreacted alcohol, the alkyl esters and glycerine leaving concentrate residue containing sterols and other unsaponifiable materials (see column 3, lines 54-71). The still residue is then saponified using sodium

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hydroxide and then dried to remove water content (see column 4, lines 38-48). The reaction mixture is then subjected to heat treatment in an inert atmosphere where high boiling volatiles such as sterols are collected by short path high vacuum distillation under reduced pressure to obtain high boiling unsaponifiables such as sterols and tocopherols (see column 6, lines 15-22).

The instant claimed invention differs from the reference that the reference does not teach about the extraction of phytosterols by different short path distillations and then solvent extraction of unsaponifiable contents. The reference also does not teach about the extraction of phytosterols from saponified product via liquid-liquid extraction and then crystallization.

Jacobs (US Patent 6,838,104) teaches a process for the production of tocotrienol compounds from biological sources such as palm oil, cereal, grains and grain oils. The first step of the process involves stripping of fatty acid from palm fatty acid distillate at a temperature between about 170° C and about 255° C (preferably between 180° C to 240° C) at an absolute pressure of between about 0.1 Torr to 2.0 Torr (preferably about 0.5 Torr to 1.5 Torr) (see the entire document especially column 4 line 64-65; column 5, lines 1-10).

The stripped residue (from above) is then subjected to a short path distillation at about 150° C to about 250° C (preferably between about 180° C to about 210° C) at an absolute pressure between about 0.005 Torr to about 0.1 Torr (preferably from about 0.01 Torr to about 0.05 Torr). The distillate of this step was again subjected to second short path distillation at temperature between 120° C and 180° C (preferably between

140° C to 160° C) at an absolute pressure of about 0.01 Torr to about 0.5 Torr (preferably from about 0.03 Torr to about 0.08 Torr) (see column 5, lines 11-35).

The resulting product is then saponified using sodium hydroxide in water. After the completion of saponification the excess water and glycerine was discarded and the saponified product was then distilled using second short path distillation at about 150° C to about 250° C (preferably about 180° C to about 210° C) at an absolute pressure of about 0.005 Torr to about 0.1 Torr (preferably about 0.01 Torr to 0.05 Torr) (see column 5, lines 36-67; and column 6, lines 1-13). The distillate was then subjected to solvent wintering for removal of sterols. In this process the distillate was dissolved in heptane, chilled and filtered. (see column 6, lines 13-20).

Robinson et al. (6,057,462) teaches a method of isolation of sterols from crude tall oil by saponification and then extracting the neutral fraction from the saponified tall oil pitch. The neutrals are then blended with hydrocarbon (pentane, hexane, heptane and isooctane, and mixture thereof) and alcohol (such as methanol, ethanol butanol, iso-propanol and mixture thereof) in addition to water at elevated temperature from about 60°C-70°C and then removing the organic layer. The organic layer was allowed to cool to about 20°C to about 30°C to produce sterol crystals (see the entire document especially column 4, lines 4-14; table II at column 5 and 6).

It would have been obvious to one skilled in the art to use the teachings of the Kirschenbauer about recovery of sterols from fatty materials by making esters and then distilling the esterified solution to give residue which is then subjected to saponification and distillation at reduced temperature to give sterol and combine with teachings of

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Jacobs about the isolation of tocotrienols using short path distillation, saponification and solvent wintering with heptane and Robinson et al. about saponification of tall oil and then extraction of phytosterol by hydrocarbon/alcohol/water and then crystallizing the organic layer by cooling to obtain pure sterol crystals as presently claimed in the invention.

Therefore, one having ordinary skill in the art at the time of invention was made would have been motivated to use teachings of the prior art about the esterification, distillation, saponification and solvent extraction to come up with a method for extraction and purification of sterols or phytosterol with greater expectation of success for extraction of pytosterols from fatty material or oil (palm oil or tall oil).

The process of esterification, distillation, saponification and extraction of sterols by liquid extraction and then crystallization were performed on either palm oil or tall oil in the prior art. This suggest that irrespective of the oil used in recovery of sterols or phytosterols, the process for recovery remains the same and obvious based on prior art.

In the absence of any criticality/unexpected results presently claimed invention is considered prima facie obvious over the prior art for the reasons cited above.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. In re opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); In re Bode 193 USPQ 12 (CCPA) 1976). A reference is not limited to working examples. In re Fracalossi 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that the instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In light of forgoing discussion, the examiner conclude that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jai P. Singh whose telephone number is 571-272-8147. The examiner can normally be reached on M-F from 8:30AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan (acting supervisor) can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jps
12/9/2005



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PRIMARY EXAMINER